

REMARKS

Applicant submits this Amendment in response to the final Office Action mailed on March 30, 2010.

In the Action, the Examiner rejected claims 31-33 and 38-44 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. In addition, the Examiner rejected claims 31-33 and 38-44 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Wallinsky (U.S. Patent No. 5,575,771) in view of Osborne et al. (U.S. Patent No. 5,690,642). The Examiner made the rejections final.

By this Amendment, Applicant amends independent claims 31 and 40 to include the limitations of dependent claims 33 and 42, respectively. As a result of the amendments to independent claims 31 and 42, Applicant also cancels claims 33 and 42. Claims 31-32, 38-41, and 43-44 are currently pending. Of these claims, claims 31 and 40 are independent.

35 U.S.C. § 112, First Paragraph, Rejection

Applicant respectfully traverses the Section 112, first paragraph, rejections of claims 31-33 and 38-44. In formulating these rejections, the Examiner states that “[t]he claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.” See Office Action at page 2.

Further, the Examiner contends that there is insufficient support in the Applicant’s specification for the “limitations stating that the anchor limits the balloon’s expansion in

comparison with the expansion in an unconstrained portion in which the anchor element is not present when the balloon changes from its contracted to its deployed state.” *Id.*

Applicant respectfully disagrees.

The purpose of the written description requirement is to ensure that the inventor had possession of the claimed subject matter at the time the application was filed. See M.P.E.P. § 2163. If a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of the filing, even if every nuance of the claims is not explicitly described in the specification, then the written description requirement is met. *In re Alton*, 76 F.3d 1168, 1175, 37 USPQ2d 1578, 1581 (Fed. Cir. 1996). The written description requirement may be satisfied using words, structures, figures, diagrams, and formulas. See M.P.E.P. § 2163.02 (citing *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997)). Indeed, in some circumstances, “drawings alone may provide a ‘written description’ of an invention as required by § 112.” *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1565, 19 USPQ2d 1111, 1118 (Fed. Cir. 1991).

Additionally, “[t]he examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant’s disclosure a description of the invention defined by the claims.” See M.P.E.P. § 2163(III)(A). In rejecting claims under Section 112, first paragraph, the examiner “must set forth express findings of fact regarding the [] analysis which support the lack of written description conclusions.” *Id.* In addition to identifying the claim limitation at issue, these findings should “[e]stablish a *prima facie* case by providing reasons why a person skilled in the art at the time the application was filed would not

have recognized that the inventor was in possession of the invention as claimed in view of the disclosure of the application as filed.” Id. (Emphasis added.)

Moreover, “an applicant is not limited to the nomenclature used in the application as filed.” See M.P.E.P. § 608.01(o). Instead, it is only required that the terminology of the claims “find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description.” Id. Indeed, as alluded to above, claims may find descriptive basis in the original disclosure, which includes “the specification with original claims and drawings, as filed.” See M.P.E.P. § 608.

As an initial matter, Applicant notes that the Office Action does not provide the required findings of fact to support the Section 112, first paragraph, rejection of claims 31-33 and 38-44. Specifically, the Examiner has failed to provide any reasons why a person skilled in the art at the time the application was filed would not have recognized that the inventor was in possession of the invention as claimed in view of the disclosure of the application as filed, as required by Section 2163(III)(A) of the M.P.E.P. Instead, the Action conclusorily asserts that the specification does not provide support for “limitations stating that the anchor limits the balloon’s expansion in comparison with the expansion in an unconstrained portion in which the anchor element is not present when the balloon changes from its contracted to its deployed state.” Office Action at page 2. In the event the Examiner maintains the Section 112, first paragraph, rejection of claims 31-33 and 38-44, the Examiner is requested to provide the necessary findings of fact and reasons required by Section 2163(III)(A) of the M.P.E.P.

Notwithstanding the above, the subject matter of the pending claims is adequately supported by the originally-filed disclosure. Figures 17A'-17B' and the corresponding written disclosure describe a balloon 115 having an anchor element 116 affixed to its interior surface. As specifically shown in Figures 17A'-17B', anchor element 116 limits expansion (or, in the case of claim 40, restrains expansion) of the surface it is affixed to when compared to the degree of expansion experienced by the opposing surface or side of balloon 115. Stated differently, when balloon 115 changes from its contracted state (shown in Fig. 17A') to its deployed state (shown in Fig. 17B'), the surface of balloon 115 to which anchor element 116 is affixed undergoes limited expansion (or, in the case of claim 40, is restrained from expanding) when compared to the expansion experienced by the opposite side surface, which does not include an anchor element. One of ordinary skill in the art therefore would understand that the application disclosure, as a whole, provides adequate written description support for "limitations stating that the anchor limits the balloon's expansion in comparison with the expansion in an unconstrained portion in which the anchor element is not present when the balloon changes from its contracted to its deployed state."

For at least these reasons, Applicant respectfully requests reconsideration and the withdrawal of the Section 112, first paragraph, rejection of claims 31-33 and 38-44.

35 U.S.C. § 103(a) Rejection

Applicant respectfully traverses the Section 103(a) rejection of claims 31-33 and 38-44 over Wallinsky and Osborne et al. Neither reference, taken alone or in combination, teaches or suggests each and every element of independent claims 31 and 40. In particular, the applied references at least fail to disclose the claimed

combination including a balloon having contracted and deployed states, an anchor element that limits (or, in the case of claim 40, restrains) expansion of the balloon in a constrained portion, wherein the “anchor element is disposed within the balloon.”

Wallinsky discloses a balloon catheter with an external guidewire. As shown in, for example, Fig. 1, catheter 10 includes an elongate flexible body 12a and a balloon 24. In addition, catheter 10 includes a guidewire 40 extending “over the *exterior* of the balloon when the balloon is inflated.” Col. 5, ll. 15-16. (Emphasis added.)

In the Action, the Examiner alleges that the guidewire 40 of Wallinsky corresponds to the claimed anchor element. See Office Action at page 3. Even if guidewire 40 may be construed to limit or restrain expansion of balloon 24, which Applicant does not concede, guidewire 40 is not disposed within balloon 24, as required by claims 31 and 40. Indeed, as explicitly depicted in, for example, Figure 1, guidewire 40 extends over an exterior of balloon 24. Accordingly, Wallinsky fails to teach each and every element of amended independent claims 31 and 40.

The Examiner has relied on Osborne et al. solely for the alleged teaching of utilizing “balloon catheters in the delivery of stent in columns 1 and 2 in order to deliver a contracted stent to its treatment location and expand the stent to meet the dimensions of the treatment site.” Office Action at page 3. This teaching fails to overcome the above-described deficiency of Wallinsky. Thus, the Examiner’s proposed combination of Wallinsky and Osborne et al. does not suggest each and every limitation of independent claims 31 and 40, and, therefore, claims 31 and 40 and their dependent claims are allowable over these references.

For at least these reasons, Applicant respectfully requests the reconsideration and withdrawal of the Section 103(a) rejection of claims 31-33 and 38-44 over Wallinsky and Osborne et al.

Conclusion

The Office Action contains characterizations of the claims and the related art with which Applicant does not necessarily agree. Unless expressly noted otherwise, Applicant declines to subscribe to any statement or characterization in the Office Action.

In discussing the specification, claims, and drawings in this Amendment, it is to be understood that Applicant is in no way intending to limit the scope of the claims to an exemplary embodiment described in the specification or abstract and/or shown in the drawings. Rather, Applicants is entitled to have the claims interpreted broadly, to the maximum extent permitted by statute, regulation, and applicable case law.

Applicant respectfully requests that this Amendment under 37 C.F.R. § 1.116 be entered by the Examiner, placing claims 31-32, 38-41, and 43-44 in condition for allowance. Applicant submits that the proposed amendments of claims 31 and 40 do not raise new issues or necessitate the undertaking of any additional search of the art by the Examiner because the amendments to these claims merely incorporate the already-examined subject matter of now-cancelled claims 33 and 42. Therefore, this Amendment should allow for immediate action by the Examiner.

Furthermore, Applicant respectfully points out that the final action by the Examiner presented some new arguments as to the application of the art against Applicant's invention. It is respectfully submitted that the entering of this Amendment

would allow Applicant to reply to the final rejections and place the application in condition for allowance.

Finally, Applicant submits that the entry of this Amendment would place the application in better form for appeal, should the Examiner dispute the patentability of the pending claims.

If the Examiner wishes to discuss this application, he is invited to contact the undersigned at (202) 408-4221.

In view of the foregoing amendments and remarks, Applicant respectfully submits that this claimed invention, as amended, is neither anticipated nor rendered obvious in view of the prior art references cited against this application. Applicant therefore requests the entry of this Amendment, the Examiner's reconsideration and reexamination of the application, and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this Amendment, and charge any required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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